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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,459	10/06/2003	Chris Rundfeldt	NY-HUBR 1230 -US	4494
24972 7590 01/16/2007 FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			EXAMINER CLAYTOR, DEIRDRE RENEE	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/16/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary****Application No.**

10/680,459

**Applicant(s)**

RUNDFELDT ET AL.

**Examiner**

Renee Claytor

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/18/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's election with traverse of Group I in the reply filed on 12/11/2006 is acknowledged. The traversal is on the ground(s) that there is no undue search burden to search both Groups I and II and that Group II encompasses treating epilepsy because epilepsy is a behavioral abnormality. This is not found persuasive because the treatment of behavioral abnormalities of Group II encompasses many abnormalities, including anxiety, depression or psychoses to name a few. Therefore, the two groups are distinct because Group I deals with a specific abnormality (epilepsy) and Group II deals with a broad category of behavioral abnormalities causing a search burden if the two groups were to be searched together.

The requirement is still deemed proper and is therefore made FINAL.

### ***Objections***

#### **Specification**

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: On pg. 1 of the specification in the second paragraph, a range is listed as "0,5 1%" and should be written as "0.5-1%". There are several instances of this mistake in the specification and should be corrected. The way that AWD 131-138 is written should be uniform throughout the specification. In some

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instances it is written as AWD 131-138 and in others it is written as AWD 131 138.

There are also several grammatical errors, as well as spelling errors throughout the specification that should be corrected.

### **Claims**

Claim 15 objected to because of the following informalities: the statement "...from about 1 to about 200 mg 1 kg..." should read "...from about 1 to about 200 mg per 1 kg....". Appropriate correction is required.

### ***Claim Rejections – 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bialer et al. (J Epilepsy Research (Jan 2001) 43, pgs. 11-58).

Bialer et al. teach that AWD 131-138 exerts anticonvulsant activities in dog seizure models of epilepsy (meeting the limitation of claim 12; pg. 12, Section 2.1). It is further taught that AWD 131-138 increases pentylentetrazol (PTZ)-induced seizure threshold in dogs by 33-59% after repeated oral administration of 5 mg/kg (meeting the limitations of claims 13-15; pg. 12, Section 2.1.1.1). Because it is taught that AWD 131-138 has anticonvulsant activities in animal models of epilepsy, it is inherently taught that AWD 131-138 would effectively treat epilepsy regardless of when it was diagnosed (meeting the limitation of claim 19).

***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bialer et al. (J Epilepsy Research (2001) 43, pgs. 11-58) as applied to claims 12-15 and 19 above, in view of Thomas (Veterinary Clinics of North America Small Animal Practice (2000), 30, pgs. 183-206).

Bialer et al. teach that AWD 131-138 exerts anticonvulsant activities in dog seizure models as described in the above rejection.

Bialer et al. does not teach the co-administration of another active ingredient or the specific type of epilepsy.

Thomas et al. teach that Phenobarbital is the initial choice of treatment for idiopathic epilepsy in dogs (meeting the limitations of claims 16-17; pg. 191, Choice of Treatment). Thomas et al. further teach that epilepsy is divided into idiopathic and symptomatic disorders (pg. 184, Epilepsy); therefore, it would be obvious that the broad term "epilepsy" falls into one of these two categories (meeting the limitation of claim 18).

It would be obvious to one having ordinary skill in the art at the time of the invention that AWD 131-138 would be successful in treating epilepsy in dogs by the teachings of Bialer et al., which teach that AWD 131-138 is effective in treating an

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animal-model of epilepsy in dogs. Furthermore, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would be obvious to co-administer another active ingredient such as Phenobarbital because it is useful in the treatment of idiopathic epilepsies as taught by Thomas et al. One would be motivated to administer the combined treatment with a reasonable expectation of success because both AWD 131-138 and Phenobarbital are taught to effectively treat epilepsy.

### ***Conclusion***

No claims are allowed.

### ***Contact Information***

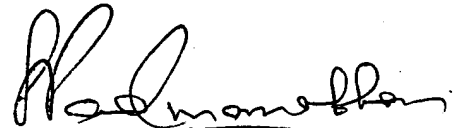
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER